

## REMARKS

Reconsideration of the rejections based upon the foregoing amendments and the following remarks is respectfully requested.

### **A. Allowable Subject Matter**

Applicants would like to thank the Examiner for indicating that claims 18 and 20 contain allowable subject matter.

### **B. Claims 1-17, 19 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over White (US 5,352,351) in view of Singhal, Doss and de Vries.**

Claim 1 specifically requires the steps of “a) applying a signal having an AC component to the sensor; b) measuring an AC response to the signal; and c) using the AC response to determine if the sensor is abused.” It is respectfully submitted that the cited references do not teach or suggest the above-recited elements of Applicants’ claim 1.

The Office Action alleges that it “would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the failsafe procedure of White to incorporate the type of measurements made by Singhal, Doss and deVries because the reliability of the measurement of glucose concentration, temperature and hematocrit through the methods of Singhal, Doss and de Vries without providing anything more than the electrodes already present...and the ability to determine if a test is usable through the Cottrell ratio as taught by White” (Office Action p. 5).

It is respectfully submitted that incorporation of the White Cottrell ratio into the measurements of Singhal, Doss and de Vries would require a series of DC response

measurements to be made in order to calculate the failsafes taught by White. Even though Singhal, Doss and de Vries all use AC measurements, there is no teaching in these references or in White, when taken alone or in combination, as to how AC measurements could be used to calculate the White Cottrell failsafe ratio. Therefore, the combination of references do not teach the claimed “using the AC response to determine if the sensor is abused.” For this reason alone, it is respectfully submitted that Applicants’ claim 1 is allowable over the references of record.

However, Applicants offer the following additional reasons why the cited combination does not make the claimed invention obvious.

Singhal, Doss and de Vries use electrode configurations that are not compatible with White

Singhal utilizes a bare oxidizable metal electrode for carbohydrate oxidation. The implantable antenna of Doss includes electrodes consisting of two parallel rows of cylindrical pins embedded in (phantom) human tissue. These electrodes are coupled to the excitation and measurement electronics using a pair of antennas held in close proximity to one another. The measurement system of de Vries uses a 4 electrode tetrapolar impedance cell to make hematocrit measurements. By contrast, White teaches the use of an electrochemical measurement cell having a two electrode configuration made from inert metals. The Office Action alleges that it would be obvious to incorporate the measurements of Singhal, Doss and de Vries with the electrochemical measurement cell of White because of “the ability to measure the temperature and hematocrit without providing anything more than the electrodes already present.” It is respectfully submitted that nothing in the prior art of record shows that the measurement techniques of Singhal, Doss and de Vries are usable with the significantly different electrode configurations of White. Furthermore, there is no teaching or suggestion in the prior art, nor an

expectation of success, that the techniques used with the oxidizable metal electrodes of Singhal, the Doss parallel cylindrical pins or the de Vries tetrapolar impedance cell could be translated to the two electrode arrangements taught by White. For example, the Doss electrode configuration, arrangement and size are important, since they contribute to the measured resistance, and the disclosed electrode arrangement bears no similarity to any of the electrodes taught by White. Similarly, de Vries teaches that “[t]o guarantee a homogeneous electrical field distribution, the distance between the electrodes (10mm) was chosen to be more than twice the radius of the conductivity cell (4mm)” (de Vries, p.466). This is significantly larger than the electrode size of electrochemical blood glucose biosensors of the type taught by White, and the blood sample volumes used by such biosensors would not cover a four electrode configuration of this scale.

It is not obvious to use DC and AC in a test using reagents

The biosensors of White all comprise electrochemical cells that use DC signals to test for analytes, wherein the DC responses are generated via reactions (usually enzymatic) that require reagents. The AC signal responses detected by Singhal, Doss and de Vries are generated directly from the parameters of interest (presence of sugars for Singhal, temperature for Doss and hematocrit for de Vries): they are direct measurements of physical and physico-chemical properties without a specifying reagent. There is no teaching, suggestion or motivation in the art, nor would it be obvious to try, to use both DC signals and signals having an AC component together in the same environment, in the presence of a reagent, and with the same electrodes. It is recognized by Applicants that claim 1 does not require a DC signal or a reagent, but the White reference relates to DC tests conducted in the presence of a reagent, therefore it would not be obvious to use the AC methods of Singhal, Doss and de Vries, which do not use reagents, with

these DC reagent-based tests. Therefore, one skilled in the art would not be motivated to combine the various tests as suggested by the Examiner, and the combination of references relied upon in the Office Action do not render Applicant's invention obvious.

It is therefore respectfully submitted that Applicants' claim 1, which specifically requires the steps of "a) applying a signal having an AC component to the sensor; b) measuring an AC response to the signal; and c) using the AC response to determine if the sensor is abused" is not shown or suggested by the references of record.

Claims 2-7 depend from claim 1 and therefore include all of the limitations of claim 1. It is therefore respectfully submitted that claims 2-7 are allowable over the references of record for at least the same reasons set forth above with respect to claim 1.

Claim 8 specifically requires "f) applying a second signal having an AC component to the biological fluid; g) measuring an AC response to the second signal; and h) combining the normalized Cottrell Failsafe Ratio and the AC response to produce an indication of whether the sensor has been abused." The patentability arguments presented above with respect to claim 1 apply equally well to claim 8. Furthermore, White does not teach the Normalized Cottrell Failsafe Ratio, but only the Cottrell Failsafe Ratio, and in any case there is no teaching or suggestion in the combination of references to combine a Normalized Cottrell Failsafe Ratio with an AC response in order to produce an indication of whether the sensor has been abused, as required by Applicants' claim 8. It is therefore respectfully submitted that claim 8 is allowable in view of the references of record.

Claims 9-17 depend from claim 8 and therefore include all of the limitations of claim 8. It is therefore respectfully submitted that claims 9-17 are allowable over the references of record for at least the same reasons set forth above with respect to claim 8

. Claim 19 specifically requires “determining a failure condition value based upon the first phase angle response the second phase angle response and a predetermined Cottrell Failsafe Ratio.” The patentability arguments presented above with respect to claim 1 apply equally well to claim 19. Furthermore, there is no teaching or suggestion in the combination of references to combine a Cottrell Failsafe Ratio with first and second phase angle responses in order to determine a failure condition value, as required by Applicants’ claim 19. It is therefore respectfully submitted that claim 19 is allowable in view of the references of record.

Claim 21 depends from claim 19 and therefore include all of the limitations of claim 19. It is therefore respectfully submitted that claim 21 is allowable over the references of record for at least the same reasons set forth above with respect to claim 19.

**C. Several references listed on Applicant’s Information Disclosure Statement were lined through by the Examiner.**

As stated in the Office Action, “the IDS submitted by applicant has several listed references lined through. Where it is clear that the reference had a date that was not usable, the reference was not submitted by applicant, a foreign reference was not submitted with a translation or explanation as required or the citation was a duplicate, the references have been lined through. If applicant feels that one or more of these references is particularly relevant to the claimed invention, the reference should be listed in an IDS with the relevance clearly noted.”

It is respectfully submitted that Applicants received a return postcard receipt from the Patent Office indicating receipt of 324 references with Applicants’ Information Disclosure Statement filed February 10, 2005 (received by the Patent Office on February 14, 2005). There

were 324 non-U.S. patent and non-U.S. published patent application references referenced on Applicants IDS's. As the Examiner is no doubt aware, Applicants are not required to submit copies of issued U.S. patents or published U.S. patent applications (see 37 C.F.R. §1.98(a)(2)(ii)). Therefore, copies of all references listed on Applicants' IDS's that were required to be submitted to the Office have been received by the Office. If any of these submitted references were lined through by the Examiner solely because he does not currently have a copy, it is respectfully requested that these references be identified and Applicant will provide a duplicate copy.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance, and respectfully request such action. Applicants respectfully request that the Examiner telephone the undersigned attorney for Applicants at 317-634-3456 if the Examiner does not find that all claims are in condition for allowance as presented herein.

Respectfully submitted,

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